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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,870	12/12/2001	Doug Hui Huang	034827-1401	6874

30542 7590 05/21/2003  
FOLEY & LARDNER  
P.O. BOX 80278  
SAN DIEGO, CA 92138-0278

EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
1637	8

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

<b>Application No.</b> 10/017,870	<b>Applicant(s)</b> HUANG, DOUG HUI
<b>Examiner</b> Shar Hashemi	<b>Art Unit</b> 1637

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 20 March 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 17 and 19-21 is/are allowed.
- 6) Claim(s) 1-16 and 18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input checked="" type="checkbox"/> Other: See Continuation Sheet .       |

Continuation of Attachment(s) 6). Other: 1. STIC Report 2. Notice to Comply.

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Preliminary Amendment (filed 11 March 2002) was received and entered as Paper No. 6. The claims pending in this application are **Claim(s) 1-21.**

### ***Sequence Rules***

2. This application does NOT comply with the sequence rules even though the sequences have been entered by the Scientific and Technical Information Center (see attached "Notice to Comply").

### ***Drawings***

3. The drawings are objected to because of the reason set forth below. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

This application contains sequence disclosures (see Figures 1-2) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Furthermore, sequence disclosures must be labeled with SEQ ID NO "identifiers."

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

***Specification***

4. The use of the trademark “BioMek” (page 15, par. 73) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The acronym "TIGR" in claim 1 renders claims 1-16 and 18 indefinite. It is unclear as to whether the acronym "TIGR" refers to the trabecular meshwork-inducible glucocorticoid response gene or another gene. Amending the claim to define the acronym "TIGR" would obviate the rejection.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5-11, 13-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al (US 5,925,748 July 20, 1999).

Stone et al disclose a method comprising the limitations of claims 1-3, 5-11, 13-16 and 18 (see whole document, especially col. 2, lines 25-46; col. 4, lines 53-67; col. 6, lines 16-45; col. 7-8, see example 1).

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9. Claims 1-3, 5-11, 13-16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Nguyen et al (US 6,475,724 B1 November 05, 2002).

Nguyen et al disclose a method comprising the limitations of claims 1-3, 5-11, 13-16 and 18 (see whole document, especially col. 3, lines 11-67; col. 4, lines 32-67; col. 23, lines 10-40; col. 26, lines 1-67; col. 33, lines 16-67; col. 48, see example 5).

***Allowable Subject Matter***

10. Claims 4, 12, 17, 19, 20 and 21 contain allowable subject matter.

A) The instant application is deemed to be directed to a nonobvious improvement over the invention patented in Stone et al (US 5,925,748 July 20, 1999). Stone et al in '748 Patent is directed to methods and kits for diagnosing a subject with glaucoma or with a predisposition for developing glaucoma. The '748 Patent is directed towards PCR amplification using the disclosed primers which specially hybridize to portions of the human trabecular meshwork induced glucocorticoid (TIGR) gene resulting in amplification of a 190 base pair sequence that contains the majority of primary open angle glaucoma mutations. The '748 Patent does not disclose primers of SEQ ID NOS: 1-8.

B) Nguyen et al in US 6,171,788 B1 disclose 5304 bp sequences which shares 100% local similarity at locus 4305 with SEQ ID NO: 1 (see Figure A of STIC report).

C) Stone et al in US 5,885,776 disclose a 190 bp sequence which shares 100% local similarity at locus 160 with SEQ ID NO: 2 (see Figure B of STIC Report).

D) Stone et al in US 5,885,776 disclose a 190 bp sequence which shares 100% local similarity at locus 10 with SEQ ID NO: 3 (see Figure C of STIC Report).

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- E) Nguyen et al in US 08/546,568 disclose a 1491 bp sequence which shares 100% local similarity at locus 1388 with SEQ ID NO: 4 (see Figure D of STIC Report).
- F) Bonaldo et al in "Normalization and subtraction: two approaches to facilitate gene discovery" Genome Res 6 (9), pages 791-806 (1996) disclose a 357 bp sequence which shares 100% local similarity at locus 213 with SEQ ID NO: 5 (see Figure E of STIC Report).
- G) Shuber in US 5,707,806 disclose a 30 bp sequence which shares 100% local similarity at locus 30 with SEQ ID NO: 6 (see Figure F of STIC Report).
- H) Stone et al in US 6,403,307 B1 disclose a 2800 bp sequence which shares 100% local similarity at locus 872 with SEQ ID NO: 7 (see Figure G of STIC Report).
- I) Lapidus et al in US 6,143,529 disclose a 37 bp sequence which shares 100% local similarity at locus 1 with SEQ ID NO: 8 (see Figure G of STIC Report).
- J) Even though the prior art teaches larger sequences that have homology with SEQ ID NOS 1-8, there is no suggestion or teaching to select primers 1-8 encoded by SEQ ID NOS: 1-8.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## CONCLUSION

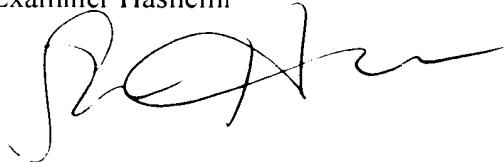
11. Claims **1-16 and 18** are rejected and claims **17 and 19-21** are allowed for the reasons set forth above.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi



Ethan Whisenant, Ph.D.  
Primary Examiner  
Art Unit 1634



**STIC REPORT**  
10/017,870  
034827-1401

**SEQ ID NO: 1**

Query Match 100.0%; Score 32; DB 4; Length 5304;

Best Local Similarity 100.0%; Pred. No. 1.3e-09;  
Matches 32; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 1 CGAATAGAGCCATAAACTCAAAGTGGTAATAA 32  
|||||||||||||||||||||||||||||

Db 4305 CGAATAGAGCCATAAACTCAAAGTGGTAATAA 4336

**FIGURE A**

**SEQ ID NO:2**

Query Match 100.0%; Score 22; DB 2; Length 190;

Best Local Similarity 100.0%; Pred. No. 0.00047;  
Matches 22; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 1 CCGTATTCTTGGGGTGGCTACA 22  
||||||||||||||||||||||

Db 160 CCGTATTCTTGGGGTGGCTACA 181

**FIGURE B**

**SEQ ID NO: 3**

Query Match 92.3%; Score 24; DB 2; Length 195;

Best Local Similarity 100.0%; Pred. No. 2.8e-05;

Matches 24; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 3 CAAACCTGGGAGACAAACATCCGT 26

||||||||||||||

Db 10 CAAACCTGGGAGACAAACATCCGT 33

**FIGURE C**

**SEQ ID NO: 4**

Query Match 88.6%; Score 31; DB 9; Length 1491;  
Best Local Similarity 100.0%; Pred. No. 8.1e-07;  
Matches 31; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 5 GCTATAAGTACAGCAGCATGATTGACTACAA 35  
|||||||||||||||||||||||||

Db 1388 GCTATAAGTACAGCAGCATGATTGACTACAA 1418

**FIGURE D**

**SEQ ID NO: 5**

Query Match 50.0%; Score 20; DB 14; Length 357;  
Best Local Similarity 100.0%; Pred. No. 0.72;  
Matches 20; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 21 GTATGGTGTGTGGATGCGAG 40  
|||||||||||||||||

Db 213 GTATGGTGTGTGGATGCGAG 232

**FIGURE E**

**SEQ ID NO: 6**

Query Match 50.0%; Score 20; DB 1; Length 30;  
Best Local Similarity 100.0%; Pred. No. 0.0096;  
Matches 20; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GCGGTCCCAAAAGGGTCAGT 20

||||||||||||||

Db 30 GCGGTCCCAAAAGGGTCAGT 11

**FIGURE F**

**SEQ ID NO: 7**

Query Match 53.7 ; Score 22; DB 4; Length 2800;  
Best Local Similarity 100.0 ; Pred. No. 0.00035;

Matches 22; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 20 TGCAGAATAGAGCCATAAACTCA 41  
|||||  
Db 872 TGCAGAATAGAGCCATAAACTCA 893

#### FIGURE G

SEQ ID NO: 8

Query Match 50.0%; Score 20; DB 3; Length 37;  
Best Local Similarity 100.0%; Pred. No. 0.0096;  
Matches 20; Conservative 0; Mismatches 0;  
Indels 0; Gaps 0;

Qy 1 GCGGTCCAAAAGGGTCAGT 20  
|||||  
Db 1 GCGGTCCAAAAGGGTCAGT 20

#### FIGURE H



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APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
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1017,870

12/12/2001

Douglas Hui Huang

034827-140

DATE MAILED:

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS  
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821–1.825 for the following reason(s):

- 1. This application fails to comply with the requirements of 37 CFR 1.821–1.825.
- 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- 4. A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

7. OTHER: Figures 1-2 contain nucleotide Sequences which lack SEQ ID NO & identifiers.

**APPLICANT MUST PROVIDE:**

- An initial or substitute computer readable form (CRF) copy of the "Sequence Listing."
- An initial or substitute paper copy of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

**FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CONTACT:**

- For Rules Interpretation, call (703) 308-1123.
- For CRF submission help, call (703) 308-4212.
- For PatentIn software help, call (703) 308-6856.

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Customer Service Center  
Initial Patent Examination Division (703) 308-1202